

## Message Text

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21

ORIGIN HEW-06

INFO OCT-01 AF-10 ARA-10 EA-10 EUR-12 NEA-10 RSC-01 ISO-00

OES-05 MED-03 /068 R

66615

DRAFTED BY DHEW/FDA/JRWEINROTH, M.D.

APPROVED BY OES/SCI/BMP: MBEAUBIEN

DHEW/OIH/MACODDING

NEA/RA:TGRANT (INFO)

EA/J:CDUNKERLEY (INFO)

AF/S:RJDOES (INFO)

ARA/MEX:JKEANE (INFO)

ARA/BC/C:AISAACS (INFO)

EUR/WE:KHSHIRLEY (INFO)

EUR/NE:CFLOYD (INFO)

----- 096348

R 052053Z DEC 74

FM SECSTATE WASHDC

TO AMEMBASSY BRUSSELS

AMEMBASSY SANTIAGO

AMEMBASSY NEW DELHI

USINT BAGHDAD

AMEMBASSY TOKYO

AMEMBASSY BEIRUT

AMEMBASSY MEXICO

AMEMBASSY PRETORIA

AMEMBASSY LONDON

UNCLAS STATE 267235

E.O. 11652:N/A

TAGS: ETRD, EIND, TBIO, BE, CI, IN, IZ, JA, LE, MX, SF

SUBJECT: RECALL OF MEDICAL DEVICE - ULTRAFILTRATION DIALYZER  
DEVICE.

1. FDA ADVISES THAT TRAVENOL LABORATORIES, INC., ARTIFICIAL  
ORGANS DIVISION, MORTON GROVE, ILLINOIS 60053, IS  
RECALLING THE ULTRA-FLO II DIALYZER (HIGH ULTRA FILTRATION),  
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PRODUCT CODE 5M1750 TO THE USER LEVEL. LOTS

NUMBER ZC68W2/W9, ZC9A/A6, ZC69A8/A9, ZC69F1 ARE SPECIFICALLY AFFECTED. HOWEVER, THE RECALL HAS BEEN EXTENDED TO INCLUDE ALL LOTS DISTRIBUTED IN THE PAST SIX MONTHS, THEREFORE, A TOTAL OF 18 LOTS ARE INVOLVED.

2. THE ULTRA-FLO II DIALYZER IS A COIL TYPE ARTIFICIAL KIDNEY USED IN HEMO-DIALYSIS. CODE 5M1750 (HIGH ULTRA FILTRATION) HAS ONE SQUARE METER OF CUPROPHANE MEMBRANE AND AT 300 ML./MINUTE BLOOD FLOW, REMOVES ABOUT ONE LITER/HOUR OF FLUID FROM THE PATIENT. THE COIL SCREENING (WHICH SUPPORTS AND SEPARATES THE COILED CUPROPHEN MEMBRANE TUBE) IN THE 18 LOTS CONTAINS STRANDS WHICH INTERSECT AT A MORE ACUTE ANGLE THAN NORMAL RESULTING IN A LOW DEGREE OF ULTRA FILTRATION WHICH APPROXIMATES THE CAPABILITIES OF THE "STANDARD ULTRA FILTRATION" COIL (5 M1751). THESE COILS ARE NOT CAPABLE OF "HIGH ULTRA FILTRATION" OF THE 5M1750 AS LABELED. THE PROBLEM IS BELIEVED TO EXIST IN AS MANY AS 50 PERCENT OF THE COILS OF THESE LOTS.

3. FOREIGN CONSIGNEES AS FOLLOWS:

TRAVENOL LABORATORIES INTERNATIONAL, DIVISION OF BAXTER/  
TRAVENOL, INC., BRUSSELS, BELGIUM AND LESSINES, BELGIUM

CODES: CASES:

AC69F1 66  
ZC69F1 49  
ZC69A9 201  
ZC69AO 239

CODES: ZC68W9 CASES: 161

HOSP. UNIV CAT., SANTIAGO, CHILE

CODE ZC68W7 CASES : 10

OFFICE OF THE DIRECTOR PROFESSOR, S.M. MEDICAL  
COLLEGE, AGRA, INDIA

CODE ZC69A3 CASES: 4  
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DIRECTORATE GENERAL OF MEDICAL SUPPLIES, BAGHDAD, IRAQ

CODE ZC68W7 CASES: 20

TRAVENOL LABORATORIES INTERNATIONAL, DIVISION  
OF BAXTER/TRAVENOL, INC., OSAKA, JAPAN

CODES: ZC69A9 CASES: 167  
ZC68W2 334

TRAVENOL LABORATORIES INTERNATIONAL, DIVISION OF BAXTER/TRA-  
VENOL, INC., BEIRUT, LEBANON

CODES: ZC-68W3 CASES: 100

TRAVENOL LABORATORIES INTERNATIONAL, DIVISION OF  
BAXTER/TRAVENOL, INC., MEXICO CITY, MEXICO

CODES: ZC68W7 CASES: 30  
ZC69F1 17

TRAVENOL LABORATORIES INTERNATIONAL, DIVISION OF BAXTER/  
TRAVENOL, INC., JOHANNESBURG, SOUTH AFRICA  
CODES: ZC68W3 CASES: 67

TRAVENOL LABORATORIES INTERNATI  
NAL, DIVISION OF BAXTER/  
RAVENOL, INC., THETFORD, NORFOLK, ENGLAND

CODES: ZC6983 CASES: 34

4. POST ARE REQUESTED TO DETERMINE IF FOREIGN CONSIGNEE  
IS FAMILIAR WITH DETAILS OF RECALL AND , IN ADDITION,  
MAY WISH TO INFORM HOST GOVERNMENT SO  
THAT THEY MAY  
TAKE SUCH ACTION AS THEY DEEM APPROPRIATE.  
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## Message Attributes

**Automatic Decaptioning:** X  
**Capture Date:** 01 JAN 1994  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** MEDICAL EQUIPMENT, RECALLS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Draft Date:** 05 DEC 1974  
**Decaption Date:** 01 JAN 1960  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Authority:** n/a  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01 JAN 1960  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
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**Film Number:** D740354-0194  
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**Locator:** TEXT ON-LINE, ON MICROFILM  
**Office:** ORIGIN HEW  
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**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
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**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
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**Review Authority:** MorefiRH  
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**Review Content Flags:**  
**Review Date:** 19 SEP 2002  
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US Department of State  
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30 JUN 2005

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**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** RECALL OF MEDICAL DEVICE - ULTRAFILTRATION DIALYZER DEVICE.  
**TAGS:** ETRD, EIND, TBIO, BE, CI, IN, IZ, JA, LE, MX, SF, TRAVENOL LABORATORIES INC  
**To:** BRUSSELS MULTIPLE  
**Type:** TE  
**Markings:** Declassified/Released US Department of State EO Systematic Review 30 JUN 2005